

**Patient leaflet in accordance with the Pharmacists' Regulations  
(Preparations) – 1986**

The medicine is dispensed according to a physician's prescription only

## **Serevent Diskus, powder for inhalation**

**Each dose contains 50 micrograms of salmeterol (as xinafoate)**

For the list of the inactive and allergenic ingredients see section 2 – “Important information about some of the ingredients of the medicine” and section 6 – “Additional information”.

**Read the entire leaflet carefully before using the medicine.** This leaflet contains concise information about the medicine. If you have further questions, refer to the physician or the pharmacist.

This medicine has been prescribed for you. Do not pass it on to others. It may harm them even if it seems to you that their medical condition is similar.

### **1. WHAT IS THE MEDICINE INTENDED FOR?**

Serevent Diskus contains the medicine salmeterol. The medicine is intended for bronchodilation in cases of reversible airway obstruction in patients with asthma or Chronic Obstructive Pulmonary Disease (COPD).

**If you are being treated for asthma (including nocturnal asthma and exercise-induced asthma), you should always be given both a Serevent Diskus and a steroid inhaler to use together.**

**Therapeutic group:** Selective beta-2-adrenoreceptor agonists.

This medicine is a ‘long-acting bronchodilator’. It helps the airways in the lungs to stay open. This makes it easier for air to get in and out. The effects are usually felt within 10 to 20 minutes and last for 12 hours or more.

Serevent Diskus helps to stop breathlessness and wheezing coming on. It does not work once you are breathless or wheezy. If that happens, you need to use a ‘fast-acting reliever’ medicine, such as salbutamol.

The medicine is supplied to you in an inhaler called the Diskus. You breathe the medicine directly into your lungs.

### **2. BEFORE USING THE MEDICINE**

**Do not use the medicine if:**

you are sensitive (allergic) to the active ingredient (salmeterol xinafoate), or to the additional ingredient lactose.

**Special warnings regarding the use of the medicine**

- **If you are using Serevent Diskus for asthma your physician will want to regularly check your symptoms.**
- **If your asthma or breathing gets worse tell your physician straight away.** You may find that you are more wheezy, you feel tightness in your chest more often or you may need to use more of the ‘fast-acting reliever’ medicine. If any of these happen, do not increase your number of puffs of Serevent Diskus. Your chest condition may be getting worse and you could

become seriously ill. See your physician as you may need a change in asthma treatment.

- Once your asthma is well controlled your physician may consider it appropriate to gradually reduce the dosage of Serevent Diskus.
- If you have been prescribed Serevent Diskus for your asthma, continue to use any other asthma medication that you are already taking. These could include a steroid inhaler or steroid tablets. Continue taking the same doses as before, unless your physician tells you otherwise. Do this even if you feel much better. **Do not stop taking your steroid inhaler (or any steroid tablets) when you start using Serevent Diskus.**
- Your physician may want to check your health regularly if you have an overactive thyroid gland, diabetes mellitus (Serevent Diskus may increase your blood sugar level) or heart disease, including an irregular or fast heartbeat.

### **Children and adolescents**

The medicine is not intended for children under the age of 4.

### **Drug interactions**

**If you are taking or have recently taken other medicines including non-prescription medicines and nutritional supplements, tell the physician or the pharmacist.**

- This includes medicines for asthma or any other medicines obtained without a prescription. This is because Serevent Diskus may not be suitable to be taken with other medicines.
- Inform your physician before using Serevent Diskus if you are currently being treated for any fungal infections with medicines containing ketoconazole or itraconazole, or if you are being treated for HIV with ritonavir. These medicines may increase the risk of you experiencing side effects with Serevent Diskus, including irregular heartbeats, or may make side effects worse.
- Beta-blockers should be avoided when taking Serevent Diskus, unless your physician tells you to take them. Beta-blockers, including atenolol, propranolol and sotalol, are mostly used to treat high blood pressure or other heart conditions. Tell your physician if you are taking beta-blockers or have recently been prescribed beta-blockers as they may reduce or abolish the effects of salmeterol.
- Serevent Diskus can reduce the amount of potassium in your blood. If this happens you may notice an uneven heartbeat, muscle weakness or cramp. This is more likely to happen if you take Serevent Diskus with some medicines used to treat high blood pressure (diuretics) and other medicines used to treat breathing problems such as theophylline or steroids. Your physician may ask for you to have blood tests to check the amount of potassium in your blood. If you have any concerns consult your physician.

### **Pregnancy and breast-feeding**

If you are pregnant or breast-feeding, think you may be pregnant or are planning to become pregnant, ask your physician or pharmacist for advice before taking this medicine.

#### **Driving and using machines**

The possible side effects associated with Serevent Diskus are unlikely to affect your ability to drive or use machines.

#### **Important information about some of the ingredients of the medicine**

This medicine contains lactose. If you have been told by your physician that you have an intolerance to some sugars, contact your physician before taking this medicinal product.

### **3. HOW SHOULD YOU USE THE MEDICINE?**

Always use the preparation according to the physician's instructions.

Check with the physician or pharmacist if you are uncertain about the dosage and treatment regimen of the preparation.

- **If you are being treated for asthma, you should always be given both a Serevent Diskus and a steroid inhaler to use together.**
- Use Serevent Diskus every day, until your physician advises you to stop.
- You will start to feel your medicine working within the first day of use.

Serevent Diskus is intended for inhalation by mouth only.

The dosage and treatment will be determined only by the physician. The usual dosage is generally:

#### **Adults with Asthma**

- The usual starting dose is 1 puff twice a day.
- For people with more severe asthma, your physician may increase your dose to 2 puffs twice a day.

#### **Children with Asthma**

- In children over the age of 4 the usual dose is 1 puff twice a day.
- Serevent Diskus is not recommended for use in children below 4 years of age.

#### **Adults with Chronic Obstructive Pulmonary Disease (COPD) including bronchitis and emphysema**

- The usual starting dose is 1 puff twice a day.
- Not applicable for children and adolescents.

#### **Do not exceed the recommended dose.**

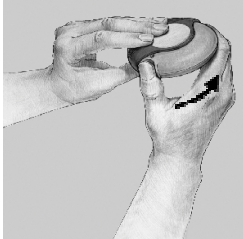
#### **Instructions for use**

- Your physician or pharmacist will show you how to use your Diskus. Not using the Serevent Diskus properly or as prescribed may mean that the medicine will not help your asthma or COPD as it should.
- The Serevent Diskus device holds blisters containing Serevent as a powder.

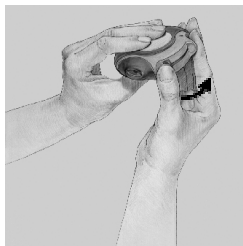
- There is a counter on top of the Serevent Diskus which tells you how many doses are left. It counts down to 0. The numbers 5 to 0 will appear in red to warn you when there are only a few doses left. Once the counter shows 0, your Diskus is empty.

### Using your Diskus

1. To open your Serevent Diskus, hold the outer case in one hand and put the thumb of your other hand on the thumbgrip. Push your thumb away from you as far as it will go. You will hear a click. This will open a small hole in the mouthpiece.



2. Hold your Serevent Diskus with the mouthpiece towards you. You can hold it in either your right or left hand. Slide the lever away from you as far as it will go. You will hear a click. This places a dose of your medicine in the mouthpiece.



Every time the lever is pushed back a blister is opened inside and the powder made ready for you to inhale. Do not play with the lever as this opens the blisters and wastes medicine.

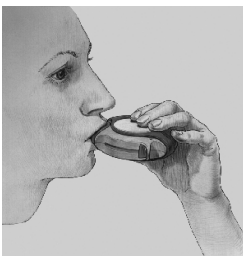
3. Hold the Serevent Diskus away from your mouth, breathe out as far as is comfortable. Do not breathe into your Serevent Diskus.
4. Put the mouthpiece to your lips; breathe in steadily and deeply through the Serevent Diskus, not through your nose.

Remove the Serevent Diskus from your mouth.

Hold your breath for about 10 seconds or for as long as is comfortable.

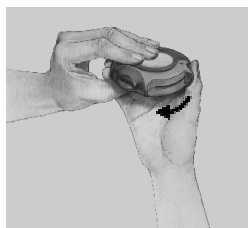
Breathe out slowly.

You may not be able to feel the texture or taste of the powder on your tongue, even if you have used Serevent Diskus correctly.



5. Afterwards rinse your mouth with water and spit it out. This may help to stop you getting thrush and being hoarse.

6. To close the Serevent Diskus, slide the thumbgrip back towards you, as far as it will go. You will hear a click. The lever will return to its original position and is reset.



Your Serevent Diskus is now ready for you to use again.

Check with your physician or pharmacist if you are not sure if you used your Serevent Diskus correctly.

### **Cleaning your Diskus**

Wipe the mouthpiece of the Serevent Diskus with a dry tissue to clean it.

### **If you accidentally inhaled a higher dosage**

It is important to use the Diskus as instructed.

If you inhaled an overdose or if a child has accidentally inhaled the medicine, refer immediately to a physician or to a hospital emergency room and bring the package of the medicine with you.

You may notice your heart beating faster than usual and that you feel shaky and/or dizzy. You may also have a headache, muscle weakness and aching joints.

### **If you forgot to use Serevent Diskus**

If you forgot to inhale this medicine at the designated time, do not inhale a double dose to make up for a missed dose. Inhale the next dose at the usual time and consult the physician.

Persist with the treatment as recommended by the physician.

**Do not take medicines in the dark! Check the label and the dose each time you take a medicine. Wear glasses if you need them.**

**If you have further questions regarding the use of the medicine, consult the physician or the pharmacist.**

## **4. SIDE EFFECTS**

As with any medicine, the use of Serevent Diskus may cause side effects in some of the users. Do not be alarmed by reading the list of side effects. You may not experience any of them.

To reduce the chances of side effects, your physician will prescribe the lowest dose of Serevent Diskus to control your asthma or COPD. These are the side effects reported by people taking Serevent Diskus.

**Allergic reactions: you may notice your breathing suddenly gets worse after using Serevent Diskus.** You may be very wheezy and cough. You may also notice itching and swelling (usually of the face, lips, tongue or throat). If you get these effects or they happen suddenly after using Serevent Diskus,

**tell your physician straight away.** Allergic reactions to Serevent Diskus are very rare (they affect less than 1 person in 10,000).

Additional side effects

**Common side effects (affect less than 1 person in 10):**

- Muscle cramps
- Feeling shaky; fast or uneven heartbeat (palpitations), headache, shaking hands (tremor). Tremors are more likely if you are taking more than one puff twice daily. These side effects do not last long and happen less as treatment with Serevent Diskus continues.

**Uncommon side effects (affect less than 1 person in 100):**

- Rash
- Very fast heart rate (tachycardia). This is more likely to happen if you are taking more than one puff twice daily
- Feeling nervous.

**Rare side effects (affect less than 1 person in 1,000):**

- Feeling dizzy
- Being unable to sleep or finding sleep difficult
- A reduction in the amount of potassium in your blood (you may get an uneven heartbeat, muscle weakness, cramp).

**Very rare side effects (affect less than 1 person in 10,000):**

- **Breathing difficulties or wheezing that gets worse straight after taking Serevent Diskus.** If this happens **stop using your Serevent Diskus.** Use your 'fast-acting reliever' inhaler to help your breathing **and tell your physician straight away**
- Uneven heartbeat or your heart gives an extra beat (arrhythmias). If this happens do not stop using Serevent Diskus but tell your physician
- Increase in the amount of sugar (glucose) in your blood (hyperglycemia). If you have diabetes, more frequent blood sugar monitoring and possibly adjustment of your usual diabetic treatment may be required
- Sore mouth or throat
- Feeling sick (nausea)
- Aching, swollen joints, or chest pain.

**If a side effect has appeared, if any of the side effects get worse or when you suffer from a side effect that has not been mentioned in the leaflet, you should consult the physician.**

Side effects can be reported to the Ministry of Health by clicking on the link "Report Side Effects of Drug Treatment" found on the Ministry of Health homepage ([www.health.gov.il](http://www.health.gov.il)) that directs you to the online form for reporting side effects, or by entering the link:

<https://sideeffects.health.gov.il/>

## **5. HOW TO STORE THE MEDICINE?**

- Avoid poisoning! This medicine and any other medicine should be kept in a closed place out of the reach and sight of children and/or infants in order to

avoid poisoning. Do not induce vomiting without an explicit instruction from the physician.

- Do not use the medicine after the expiry date (exp. date) appearing on the package. The expiry date refers to the last day of that month.
- Do not store above 30°C. Store in the original package.

## **6. ADDITIONAL INFORMATION**

- In addition to the active ingredient, the medicine also contains lactose (which contains milk proteins).
- What does the medicine look like and what is the content of the package – The Diskus is packaged in a carton. Each Diskus contains 60 inhalations.
- License Holder: GlaxoSmithKline (Israel) Ltd., 25 Basel St., Petach Tikva.
- Manufacturer: Glaxo Wellcome Production, Evreux, France.
- Registration number of the medicine in the National Drug Registry of the Ministry of Health: 067-16-28303

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*Serevent Dis PT v4B*